MEP National Network™

CONNECTICUT SUCCESS STORY

COMMITMENT TO WORLD-CLASS SERVICE LEADS TO SUCCESSFUL RECERTIFICATION

ABOUT BEEKLEY CORP. Founded in 1934 as a printing company, Connecticut's Beekley Corporation has emerged as a leading global supplier of niche medical and hospitality products. More than 90 years later, the company remains privately owned, with a team of 104 people, 70 percent of whom are female, operating across two distinct divisions at the Beekley Growth & Innovation Center in Bristol, Connecticut. Beekley Medical is a medical device manufacturer whose goal is 'to help positively impact patients' lives and improve clinical outcomes.' Beekley takes pride in delivering world-class customer care with medical products that enhance accuracy, communication, productivity, and patient care.
Its team focuses on researching and developing simple, cost-effective, and disposable medical imaging products for procedures such as mammography, CT scans, MRIs, radiation therapy, and breast biopsies for over 8,000 customers worldwide.
Prestige Lane Hospitality Brands, a division of Beekley Corporation, produces specialty print products for hotels, resorts, and casinos to enhance customer service and boost revenues. The company is proud to have been repeatedly named one of Connecticut's "Best Places to Work."
Beekley Medical is certified in ISO 13485:2016, the standard for the Quality Management System regarding the design and manufacture of medical devices, ensuring they meet regulatory and customer demands for safety and efficacy.

THE CHALLENGE. Recognizing the critical role its medical products play in patient care, Beekley Medical prioritizes rigorous standards and proactive process improvements across the organization, fostering both growth and exceptional service.
Beekley has retained its ISO 13485 certification since 2003. To evaluate compliance with its Quality Management System in preparation for the recertification audit, Beekley's leadership team sought external assistance to conduct the required Internal Quality Audit for 2023.

The IQA would assess the effectiveness of the company's QMS, identify any nonconformities, seek opportunities for continual improvement, determine necessary corrective actions, and provide management with feedback on whether Beekley's QMS was being implemented effectively and efficiently.

MEP CENTER'S ROLE. Building on their successful multi-year relationship with CONNSTEP, Connecticut's MEP, Beekley engaged Business Development Advisor Prakaithip Romanow to facilitate their IQA.
A third-party CONNSTEP consultant was selected to conduct the audit process, offering an objective, external perspective on Beekley's QMS and providing a roadmap to assist the company in preparing for ISO 13485 recertification. The audit examined three key areas: Beekley's management and QMS functions, product R&D activities, and its production and support processes.
Dozens of Beekley's Quality System Procedures were audited during the three-day IQA, which included:

- • Quality objectives
- • Control of documents
- • Planning of product realization
- • Contamination control

RESULTS

1000000

2000

209500

75000

5

CONTACT US

350 Church Street
10th Floor
Hartford, CT 06103-1126

(860)513-3204

www.connstep.org

CONNSTEP

• Reporting to regulatory authorities
• Design and development planning
• Cleanliness of product
• Purchasing information
• Control of nonconforming product

The auditor found that the company's QMS was "effective in managing and attaining objectives/targets," and "exceeds minimal compliance required with continuous improvement activities interwoven with QMS processes."

The IQA did not result in any major QMS nonconformances. Any minor findings were promptly addressed by conducting a root cause analysis and taking corrective action to ensure that updated processes met the QMS requirements moving forward. Beekley management took the opportunity to retroactively assess and update previous documentation in order to comply with the quality standard and provided employee training for the implementation of any new procedures.

The team assessed the observations and areas for improvement to identify quick fixes, preventive strategies, and proactive solutions designed to avert future issues.

Implementing procedural changes and taking proactive measures on items noted in the IQA report completed by the CONNSTEP consultant directly contributed to Beekley successfully retaining its quality certification.

"“As a medical device manufacturer, it is imperative that we have qualified professionals conducting our internal audits to this stringent ISO 13485 standard, as this audit has a direct impact on the success of our recertification. Our consultant is very knowledgeable with a wealth of experience who we see as an important partner in our success. CONNSTEP has been a valuable resource to Beekley over the years and has provided great service and support to ensure we continue to achieve our goals.”"

-Kate Chase, Director of Quality and Regulatory